

Medicines (Amendment) Bill

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Bill No: 5/1998

Read the first time: 14th January 1998

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Medicines (Amendment) Bill

Bill No. 5/1998

Read the first time on 14th January 1998.

An Act to amend the Medicines Act (Chapter 176 of the 1985 Revised Edition).

Be it enacted by the President with the advice and consent of the Parliament of Singapore, as follows:

Short title and commencement

1. This Act may be cited as the Medicines (Amendment) Act 1998 and shall come

into operation on such date as the Minister may, by notification in the *Gazette*, appoint.

New sections 19A and 19B

2. The Medicines Act is amended by inserting, immediately after section 19, the following sections:

“Protection of confidential supporting information about innovative medicinal product

19A.—(1) Where the licensing authority receives, or has received not more than 5 years before the commencement of the Medicines (Amendment) Act 1998, an innovative medicinal product application and confidential supporting information, the licensing authority, during the protected period in relation to that confidential supporting information —

- (a) shall take reasonable steps to ensure that that confidential supporting information is kept confidential to the licensing authority; and
- (b) shall not use that confidential supporting information for the purposes of determining whether to grant any other application.

(2) For the purposes of this section and section 19B, unless the context otherwise requires —

“application” means an application for a product licence;

“confidential information” includes —

- (a) trade secrets; and
- (b) information that has commercial value that would be, or would be likely to be, diminished by disclosure;

“confidential supporting information” means confidential information given —

- (a) in, or in relation to, an innovative medicinal product application; and
- (b) about the medicinal product that is or was, as the case may be, the subject of that application;

“innovative medicinal product application” means —

- (a) in relation to an application made after the commencement of the Medicines (Amendment) Act 1998, an application that refers to a substance —